

JUL 3 0 1999

Food and Drug Administration Rockville MD 20857

Ms. Robin Lester P. O. Box 2302 McCall, ID 83638

1489 '99 AUG -2 P1:18

Dear Ms. Lester:

This is in response to your letter dated July 17, 1999, concerning the use of recombinant Bovine Growth Hormone (rBGH) in dairy cows.

Thank you for sharing your concerns on this issue. The use of drugs in livestock and poultry is strictly regulated. Before any drug intended for use in animals is approved, it must undergo extensive chemical and toxicological testing which must demonstrate that the food from these animals is safe for human consumption.

Bovine somatotropin (bST) was approved by the Food and Drug Administration (FDA) in 1993. The recombinant, or genetically engineered form of bST (rBST) is virtually identical to a cow's natural somatotropin, a hormone produced in its own pituitary gland that stimulates milk production. Since bST is a protein-based hormone, rbST is broken down during digestion, which makes it biologically inactive and incapable of having any effect in humans or animals. Over 120 studies were reviewed by FDA scientists that examined the safety of milk and meat from dairy cows treated with rbST. They concluded that there was no increased health risk to consumers.

I am enclosing materials which provide further information concerning this matter. In addition, I am forwarding your letter to Dockets Management Branch for inclusion in Docket Number 98P-1194 -- Withdrawal of NADA Approval for Posilac -- rBGH. Please visit our Internet Home Page at http://www.fda.gov/cvm.

Sincerely yours,

Karen A. Kandra

Consumer Safety Officer

Center for Veterinary Medicine

Laren a. Kandra

Enclosures

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989-1194

July 17, 1999

Dear Sir:

I am writing to protest allowing the dairy farmers the use of rBGH when so many questions remain unanswered.

Currently, our dairy farmers have an abundance of dairy products. Since the prices charged for milk do not fluctuate with the market like other products, dairy farmers should not have to use artifical methods to produce more milk.

In addition, I oppose the use of rBGH for the following reasons:

the study used to approve its use was not published or subject to review

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No other country has approved its use after reviewing the same studies that the FDA reviewed, specifically, Canada, Japan, the European Union, Australia and New Zealand

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What are the long term effects of its use, especially when it is absorbed through the intestinal wall

We need to have labeling so we can avoid it if we so desire.

Please reconsider allowing the use of rBGH immediately.

Sincerely,

Robin Lester

Bx 2302 Mclau, ID 83638 HSCOPL



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